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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
PRATS, FRANCISCO CHANDLER

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 09/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/031,520	QI ET AL.	
	Examiner	Art Unit	
	Francisco C Prats	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-56 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-56 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-56 are presented for examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the claims are directed to products whose methods of use include *in vivo* treatment of cancer, improvement of red blood cell counts, irradiation protection, DNA repair, immune stimulation, and activation of dendritic-like cells. However, the specification as filed fails to provide any specific guidance with respect to the treatment regimes recited in the preambles of the product claims. The specification provides no specific discussion regarding possible

or desirable modes of administration for the various ailments encompassed. Moreover, while the experiments using human experiments use oral administration of the claimed agent, the experiments using human subjects do not state anything about dosages used, and no empirical data is provided to support the results presented. Similarly, while the specification alleges certain therapeutic utilities for the claimed agent, the specification fails to discuss specific disease conditions which can be treated by the claimed agent. In sum, because the specification as filed fails to provide specific disclosures regarding the uses to which the claimed products can be put, it is clear that applicant was not in possession of the claimed subject matter at the time the application was filed.

Claims 1-49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification provides a method of making the claimed agent. However, as discussed above, the specification fails to provide sufficient guidance such that the skilled artisan would

be able to use the claimed invention. As discussed above, the specification does not discuss which specific disorders can be treated with the claimed agent. For example, because there are numerous different types of cancer caused by numerous different mechanisms, cancer treatment is notoriously unpredictable, and the artisan of ordinary skill would not have reasonably expected the claimed agent to be active against all cancers. While applicant provides data demonstrating activity against certain cell lines *in vitro*, the specification does not provide any guidance as to which cancers are treatable using the claimed agent. That is, applicant's specification leaves to the practitioner the task of interpreting the *in vitro* results, so as to determine a specific therapeutic application of the claimed agent. That is, the specification's lack of guidance as to potential patients invites the practitioner to experiment to determine which ailments are treatable using the claimed agent and which are not.

Similarly, in the paragraph spanning pages 2 and 3, the specification explicitly invites the practitioner to experiment to determine suitable dosages, rather than providing specific guidance. This lack of specific guidance is underscored by the fact that those experiments using human subjects do not state the actual dosages used to achieve a therapeutic result.

Moreover, the as-filed specification provides almost no guidance as to suitable or preferred modes of administration (i.e., oral, parenteral, intramuscular, etc.).

Lastly, applicant's disclosure of therapeutic compositions is limited to extraction from *Spirulina*, whereas the bulk of applicant's claims encompass the use of any blue-green algae, i.e., any cyanobacteria. In view of the fact that the cyanobacteria contain various genera having widely differing properties, the artisan of ordinary skill would expect to have to undertake essentially a trial and error process to determine which cyanobacteria will or will not work according to the claims. Such a trial and error process clearly amounts to undue experimentation. In sum, because of the lack of specific guidance provided in the specification as filed, undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of specific guidance; unpredictability in the art; and breadth of the claims. *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). A holding of lack of enablement is therefore required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-56 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors. Confusing terminology includes the recitation "a dry powder of blue-green algae." It is confusing whether this refers to blue-green algae in powder form, or whether it encompasses any powdered material obtained from blue-green algae. Similarly, the recitation "cellular walls-breaking" appears to mean breaking cell walls, but this is not clear. Similarly, the recitation "adjusting the filter" appears to mean adjusting the filtrate, but again the meaning is not clear. Similarly in claims 3 and 4, and their later corresponding claims (e.g., claims 10 and 11), the recitation "is used as 8-15 times as that of said dry powder" is confusing. It appears the recitation should read

-- is [used as] 8-15 times [as that] by weight of said dry powder --.

Also, the recitation "if necessary" is indefinite because it is not clear what the criteria for necessity are.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-55 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Hayashi et al (U.S. Pat. 5,585,365).

The reference discloses a product which appears to be identical to the presently claimed product, based on the fact that the prior art product is made by essentially the same process as the claimed product -- hot water extraction of dried *Spirulina* cells under stirring conditions at 70 to 100 degrees C, followed by extraction under acidic conditions, followed by drying. See column 2, lines 4-55. Note also the description of the prior art product's antiviral activities. Consequently, the claimed product, as well as the method of preparation, appears to be anticipated by the reference.

However, even if the reference product and the claimed product are not one and the same and there is, in fact, no anticipation, the reference product would, nevertheless, have rendered the claimed strain obvious to one of ordinary skill in the art at the time the claimed invention was made in view of the fact that the reference discloses the desirability of using the claimed steps to make a product having the claimed therapeutic properties, any nominal difference between the claimed product and the prior art product being expected differences between batches and or differences occurring due to

nominal or optimized variations in the process steps. Thus the claimed invention as a whole was clearly *prima facie* obvious especially in the absence of sufficient, clear, and convincing evidence to the contrary.

With respect to the propriety of this type of alternative rejection, note that MPEP § 2113 states that:

> . . . [w]hen the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith. *In re Brown*, 59 CCPA 1063, 173 USPQ 685 (1972).

MPEP § 2113 also clearly states that

> 'The Patent Office bears a lesser burden of proof in making out a case of *prima facie* obviousness for product-by-process claims because of their peculiar nature' than when a product is claimed in the conventional fashion. *In re Fessmann*, 180 USPQ 324 (CCPA 1974)."

Claim Rejections - 35 USC § 103

Claims 50 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayashi et al (U.S. Pat. 5,585,365).

Hayashi discloses a process comprising hot water extraction of dried *Spirulina* cells under stirring conditions at 70 to 100

degrees C, followed by extraction under acidic conditions, followed by drying. See column 2, lines 4-55. Hayashi differs from the claims in that the 10% TCA precipitation step (column 2, lines 44-47), while resulting in a pH of less than 7 as recited in claim 50, would result in a much lower pH than the 3.8-4.2 recited in claim 56. However, the artisan of ordinary skill clearly would have recognized that performing extractions at different pH values would affect the properties of the resulting product. Thus, recognizing that extraction pH was a result-effective parameter, the artisan of ordinary skill clearly would have been motivated to have optimized that parameter to have produced a *Spirulina* hot water extract having maximal therapeutic efficacy. Therefore, the determination of a suitable pH for the acidic extraction of *Spirulina* according to the methods of Hayashi clearly must be considered an obvious optimization of Hayashi's process, and therefore unpatentable under § 103(a). Absent some demonstration of an unexpected result coming from the claimed extraction pH, a holding of *prima facie* obviousness must be maintained.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 703-308-3665. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 703-308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Francisco C Prats
Primary Examiner
Art Unit 1651

FCP